

number of oral presentations, we may need to limit the time allotted for each oral presentation (e.g., 5 minutes each). Depending on the content of the presentations, the time allotted for oral presentations may vary. We request that interested persons and groups having similar interests consolidate their requests for oral presentation and present them through a single representative. If you need special accommodations due to a disability, please inform us (see Table 1 and **FOR FURTHER INFORMATION CONTACT**).

We will also accept registration onsite; however, space is limited. Onsite registration will be accepted on a first-come, first-served basis and will be closed when the maximum seating capacity is reached. Requests for an opportunity to make a presentation from individuals or organizations that did not register in advance to make an oral presentation may be granted if time permits.

Persons who registered in advance for the hearing should check in at the onsite registration desk between 8:30 and 9 a.m. Persons who wish to register onsite on the day of the hearing should do so at the registration desk between 8:30 and 9 a.m. We encourage all participants to attend the entire day.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see Table 1) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: August 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Veterinary Medicine Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Veterinary Medicine Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 19, 2010, from 1 p.m. to 5:30 p.m. and on September 20, 2010, from 8 a.m. until 6 p.m.

Location: Rockville Hilton, 1750 Rockville Pike, Rockville, MD 20852, 301-468-1100.

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, FAX: 240-276-9020, email: aleta.sindelar@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512548. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On September 19, 2010, the committee will receive an orientation on both general scientific issues surrounding genetically engineered animals and the statutory and regulatory constraints under which the Agency must operate. On September 20, 2010, the committee will consider issues regarding the safety and effectiveness of

the new animal drug that is the subject of a new animal drug application (NADA) concerning AquaAdvantage salmon produced by AquaBounty Technologies, Inc. These genetically engineered Atlantic salmon are intended to grow faster than conventionally bred Atlantic salmon.

Two background documents entitled "An overview of Atlantic salmon, its natural history, aquaculture, and genetic engineering" and "The VMAC Meeting on Science-Based Issues Associated with AquaAdvantage Salmon" can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>.

In a separate notice published elsewhere in this issue of the **Federal Register**, FDA is announcing that it will hold a public hearing on the labeling of food, including naming of the food, from the AquaAdvantage salmon on September 21, 2010. This public hearing will allow the public to comment on the application of food labeling principles to food from the AquaAdvantage Salmon, if the NADA is approved. An overview of the labeling issues to be addressed is described in "Background Document: Public Hearing before the Commissioner on the Labeling of Food Made from the AquaAdvantage Salmon" at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>.

FDA anticipates making the meeting materials available approximately 16 days before this meeting, but in any event no later than 2 business days before the meeting at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting.

Additional information regarding the Center for Veterinary Medicine's (CVM's) regulatory oversight of genetically engineered animals can be found at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm>.

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of

Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 16, 2010. Oral presentations from the public will be scheduled between approximately 2:45 p.m. and 4 p.m. on September 20, 2010. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before September 7, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 9, 2010.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you

require special accommodations due to a disability, please contact Aleta Sindelar at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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